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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/604,378	06/27/2000	Nick W. Warne	GI-5238BA	5593
30623	7590	03/04/2004	EXAMINER	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			SEHARASEYON, JEGATHEESAN	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/604,378	<b>Applicant(s)</b> WARNE ET AL.	
	<b>Examiner</b> Jegatheesan Seharaseyon	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 October 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,4 and 11-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 3,16-18 and 26-29 is/are allowed.
- 6) ☒ Claim(s) 1,4,11-15, 19-25 and 30-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

1. This office action is in response to the amendment and remarks filed on 10/28/03. Claim 1 has been amended. Thus, claims 1, 3, 4 and 11-35 are pending and examined.
2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph maintained***

3. Rejection of Claims 1, 4, 11-15, 19-25 and 30-35 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating oral mucositis with IL-11 in a topical formulation, does not reasonably provide enablement for a method for treating all mucositis with IL-11 in topical formulations is maintained for is maintained for reasons of record of the Office Action of 7/30/2003. Applicant's arguments, filed 10/28/03, with respect to rejection of claims 1, 4, 11-15, 19-25 and 30-35 has been considered fully but is not persuasive. Applicant contends that one reasonably skilled in the art could make or use the invention from disclosures in the application coupled with information known in the art. However, the art accepted definition for "topical formulations" are directed to those formulations directly applied to skin or for external application (see U. S. Patent No: 6, 190, 691, Column 43-44) and contradicts Applicants' definition of "topical" (see specification page 8, lines 25-27). Thus, the information known in the art would direct the application IL-11 formulations of the instant invention for direct application (e.g: skin) compared to the disclosure, which contemplates other modes of administration including infant formula (claim 15) and formulations comprising enteric coating (claim 34). Therefore, it is unclear how the

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administration of a topical formulation will be able to treat gastrointestinal mucositis. Since no guidance has been provided with respect to how a topically administered formulations would reach the gastrointestinal tract to treat mucositis, it would require an undue amount of experimentation for one of skilled in the art to practice the claimed invention.

Given the breadth of claims 1, 4, 11-15, 19-25 and 30-35 in light of the unpredictability of the art as determined by the lack of working examples, the level of skill of the artisan, and the lack of guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention to treat gastrointestinal mucositis using a topical formulation containing IL-11.

4. Claims 3, 16-18 and 26-29 are allowable over prior art.

#### **Contact Information**


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS

  
GARY KUNZ  
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